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[REDACTED] EXAMINER

MEHTA, ASHWIN D

[REDACTED] ART UNIT

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1638

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15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/772,520	GARING, FRANCIS L.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1,5,7-10,12,13 and 21 is/are allowed.
- 6) Claim(s) 2-4,6,11,14-20 and 22-31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. The finality of the Office action mailed 23 January 2003 is withdrawn, and the following Non-Final Office action is set forth.

NOTE: On page 2 of the Appeal Brief submitted 30 June 2003, Applicant indicates that an amendment under 37 CFR 1.116 was filed concurrently therewith. However, the nature of the amendment was not stated. On page 6 of the Appeal Brief, in the first paragraph, Applicant indicates that claim 4 has been cancelled. However, since Applicant has not requested its cancellation, claim 4 remains pending.

2. The objection to claims 22 and 23 is withdrawn.
3. The rejection of claim 21 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of Applicant's arguments presented in the papers received 30 April 2003 and 18 November 2002, and upon further consideration.

Claim Objections

4. Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form.

Claim 26 attempts to limit the hybrid plant of claim 25 by requiring it to be an F₁ hybrid corn plant. However, the plant of claim 25 is the first generation progeny of the cross of two

distinct inbred plants, and therefore is an F₁ hybrid plant. Claims 25 and 26 are directed to the same plant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3, 4, and 14 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 23 January 2003. Applicants traverse the rejection in the papers submitted 23 April 2003 and 30 June 2003. Applicant's arguments have been fully considered but were not found persuasive. Claims 2, 6, 11, 15-20, 22-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the rejection of claims 3 and 14: Applicant argues that while the population of claim 2 is directed to a population of seed of corn variety I026458, it is not necessary that the population be an essentially homogeneous population of seed, and that a population may not be essentially homogenous yet still be a population (Appeal Brief, page 6, 2nd full paragraph). However, it is noted that the definition for "essentially homogeneous populations of inbred seed" on page 5 includes a broad limitation followed by narrow limitations. A broad range or limitation together with a narrow range or limitation that falls within the broad range or

limitation is considered indefinite, since this does not clearly set forth the metes and bounds of the patent protection desired.

Applicant provides definitions for “population” and “homogeneous,” and argues that a collection of seed may have a quality or characteristic in common, e.g., be of variety I026458, yet not be of uniform structure or composition throughout. Applicant continues, arguing that a collection of seed therefore may at one time have a quality or characteristic in common, e.g., be of variety I026458, yet not be of uniform structure or composition throughout (Appeal Brief, page 6, 2nd full paragraph). Applicant also argues that a population of plants grown from the seed of corn variety I026458 could vary in size or other characteristics due to environmental or other conditions, but still constitute a population of corn plants produced by growing the seed of corn variety I026458. Applicant argues that “essentially homogeneous” therefore further defines the scope of the claim and is not indefinite (Appeal Brief, page 7, 2nd full paragraph). However, the rejection is not based on such an issue, and was not raised in the previous Office actions. Applicant appears to be redefining “essentially homogeneous,” in that Applicant appears to be arguing that the recitation is referring to the non-uniform size and shape of individual I026458 plants. However, this is not the definition of “essentially homogeneous” as discussed in the specification. It is noted that the discussion of “essentially homogeneous populations of inbred seed” on page 5, lines 15-19, indicates that such populations can have other types of seed. The rejection, currently and in previous Office actions, was not applied because of the non-uniform nature of individual I026458 seeds and plants.

Regarding claim 4: Applicant submits that the claims are not indefinite as set forth in the previous response (response received 30 April 2003, page 2, 3rd full paragraph). The rejection is

maintained for the reasons of record stated in the previous Office actions. Further, the specification does not define “essentially free,” making the metes and bounds of claim 4 unclear.

In claim 2: the recitation “population of seed of the corn variety I026458” renders the claim indefinite. It is unclear exactly when a population can be defined as a population of I026458 seed and not a population of another seed variety. The paragraph bridging pages 5-6 of the specification states that inbred seed “generally” forms at least about 97% of total seed. The recitations “generally” and “at least about” leave the explanation open to encompass any other percentage of inbred seed. The very next sentence indicates that a population of inbred corn seed can contain 15% or less of inbred seed, and this would be indistinguishable from a small fraction, “generally” less than 2% and preferably less than 1% of inbred seed in a population of hybrid seed. If a population contains a greater percentage of seed A than seed B, is this still defined as a population of seed B, rather than a population of seed A? Applicant’s discussion of “population” indicates that a population containing 85% of seed A and 15% of seed B can be defined as both a population of seed A and a population of seed B. It is also not clear what is meant by the term “generally” in the context of the definition for “population.”

In claims 6 and 11: the recitation “in accordance with” renders the claims indefinite. The meaning of this recitation is not exactly clear, and makes the metes and bounds of the claims unclear.

In claims 15, 17, and 20: the recitation “capable of expressing” in line 1 of claim 15 and line 2 of claims 17 and 20 renders the claims indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is

suggested that the recitation in claim 15 be replaced with --having--, and in claim 20 with --has--. Similarly, the recitation “is capable of regenerating” in line 2 of claim 17 renders it indefinite. It is suggested that the recitation “the tissue is capable of regenerating plants capable of expressing” be replaced with --plants, when regenerated from said tissue culture, have--.

In claims 16 and 27: the claims broaden the scope of the claims from which they depend. The claims add on a gene or locus to the genome of the plant of their parent claims. There is no indication as to how the plants acquired the genes, and the plant of their parent claims does not possess the gene or locus. It is suggested that claim 16 be amended to recite that the plant was produced from the plant of claim 15, and to indicate how the cytoplasmic or nuclear gene conferring male sterility was introduced into the plant of claim 8. Claim 27 should be similarly amended.

In claim 18: the “derived from” in line 1 renders the claim indefinite. It is not clear how the cells are derived from the recited tissues. It is suggested that the term “derived” be deleted, or replaced with the term --isolated--.

In claim 19: the recitation “the regenerable cells comprise protoplasts” renders the claim indefinite, since protoplasts are not cells. It is suggested that the recitation, “protoplasts or” be deleted from claim 19, and that claim 17 be amended by inserting --produced from cells or protoplasts-- in line 1 after “cells.”

In claim 22: the claim is improperly dependent on claim 21. Claim 22 recites a new process. However, to be properly dependent on claim 21, claim 22 should recite how the process of claim 21 is further limited. It is suggested that claim 22 be amended by deleting the recitation, “further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred

corn plant with a second, distinct inbred corn plant”, and inserting the recitation, --, and said second parent corn plant is a distinct inbred corn plant-- in line 4 after “PTA-3228”.

In claim 28: the article “a” in the recitation “wherein the single locus was stably inserted into a corn genome” renders the claim indefinite. The recitation does not make clear if the genome is that of I026458 or that of a different corn plant.

In claim 30: the recitations, “yield enhancement,” “improved nutritional quality,” and “enhanced yield stability” are relative terms that have no definite meaning, and make the metes and bounds of the claim unclear.

6. Claims 3, 4, 14, 24-31 remain and claims 2, 6, and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 23 January 2003 under item 6. Applicant traverses the rejection in the papers received 30 April 2003 and 30 June 2003. Applicant’s arguments were fully considered but were not found persuasive. The rejection has been withdrawn from claim 21, upon further consideration.

The claims are broadly drawn towards an essentially homogeneous population of seed of corn variety I026458, or a population of I026458 seed essentially free of hybrid seed; an essentially homogeneous population of corn plants produced by growing seed of I026458; any hybrid corn seed produced by crossing corn plant I026458 with any second, distinct inbred corn plant; any hybrid corn plant produced by growing said hybrid seed; inbred corn plant I026458

further comprising any single locus conversion; a method of producing inbred corn plant derived from corn variety I026458 comprising crossing I026458 plants with any second corn plant, and crossing the progeny with itself or any other plant to produce further progeny.

The specification describes numerous morphological and physiological characteristics of corn plant I026458 (page 24, line 1 to page 29, line 5). The specification also indicates that essentially homogeneous populations of inbred seed are those in which the inbred seed forms about 90% to about 100% of the total seed (page 5, lines 15-19).

However, in those populations where I026458 seed forms less than 100% of the population, the identity of the remaining seed is unknown, yet the claims encompass all the individuals of the population. The specification does not describe the non-I026458 seed of the claimed essentially homogenous populations, or the hybrids of the populations that are “essentially free” of them.

The specification also does not describe any hybrid corn plants produced by crossing I026458 with other corn plants, except for a hybrid designated “7041221” (page 56, line 12 to page 59, line 5). The descriptions of I026458 and 7041221, however, do not provide any information concerning the description of all other hybrids. In addition, a written description of each of the RFLP and isozyme markers is not provided. While the markers are named, this is not sufficient to describe them.

The description of I026458 is also not indicative of any transgenic I026458 plant or I026458 plants comprising single gene conversion(s). The plants may be altered from I026458 in any of its traits. However, the specification does not describe single locus conversions and single transgenes that have the ability to alter any given maize plant trait. For example, single

locus conversions or transgenes that govern yield enhancement or enhanced yield stability are not described. The transgenes, such as those that encode transcription factors, may also affect more than one trait. Descriptions of such transgenic plants are not presented. The claims drawn towards preparing transgenic maize cells are included in this rejection, as all of the products required for the method are not described. Further, methods to make the claimed plants do not provide a description of all the morphological and physiological traits of the plants themselves. Given the breadth of the claims encompassing all hybrid corn seeds produced by crossing I026458 to any other maize plant, I026458 plants comprising any single locus conversion or any transgene, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

Regarding claims 3 and 14, Applicant argues that claim 3 is a proper dependent claim, and that claim 2 has not been rejected (Appeal Brief, page 9, 2nd full paragraph). Claim 2 has now been included in the rejection, as other varieties of seed, which are not described, apparently can be in the claimed population of seed of the corn variety I026458, as discussed above. Applicant also argues that a population is a group of individuals sharing a common characteristic and need not be substantially homogeneous (Appeal Brief, page 9, 2nd full paragraph). However, Applicant has previously argued that a population may potentially include a small amount of other seed (response received 18 November 2002, page 5, 3rd full paragraph). The specification also indicates that essentially homogeneous populations of inbred seed contain other seed (page 5, lines 15-19). As the claim encompasses populations that contain other seed, all of the individuals of the population do not all share common characteristics.

Regarding claim 14, Applicant argues that “essentially homogeneous” properly modifies “population,” and that populations of corn plants produced by growing seed of I026458 have not been alleged as undescribed (Appeal Brief, page 9, 2nd full paragraph). However, an essentially homogeneous population of plants can contain more than one type of plant. While plants grown from I026458 seed can only produce I026458 plants, the claimed population includes other types of plants, which are not described.

In the Appeal Brief received 30 June 2003, Applicant again argues that the hybrid seeds and plants of claims 22-24 are described because they have I026458 as a parent and that they have inherited half of their genetic material from I026458 (Appeal Brief, page 10, 1st paragraph). The Examiner maintains that the claimed hybrids will not have the same morphological and physiological characteristics as I026458. I026458 can be crossed with any other inbred corn plant to produce the claimed hybrids. The claimed hybrids then will express a combination of morphological and physiological characteristics that are different from each other, and which are also different from those expressed by I026458. That all hybrids will inherit half of their alleles from I026458 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of I026458 with any of the traits that it expresses. Further, the claimed hybrids will inherit the other half of their genetic material from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from I026458, or their products, will be affected by or interact with the alleles or their products inherited from the other parent. The expressed gene products will depend on the combination of the two alleles from each parent at each locus, whether the allele is dominant or recessive, and

the epigenetic effects of other genes. The fact that any hybrid plant will inherit half of its alleles from I026458 then does not provide sufficient description of the morphological and physiological characteristics expressed by each and every hybrid plant.

Applicant also argues that the entire genetic contribution of corn plant I026458 is described by way of deposit of seed of I026458 with the ATCC, and believe that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants. In support of this argument, Applicant cites the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposited material (Appeal Brief, page 10, 1st paragraph). However, in the patent application considered in that decision, a function was correlated with the structure of the product that was deposited. Here, the functions of the claimed hybrid plants have not been correlated to the half of their genetic material originating from the deposited I026458 seed. The function of the plant grown from an I026458 seed is correlated with the structure of its entire genome, not just one half. Further, half of the alleles of the hybrid are inherited from the other parent. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited I026458 seed.

Applicant continues, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that a name alone does not satisfy written description if structural features commonly possessed by members of the genus are not defined. Applicant argues that here, all of the members of the claimed genus of hybrids having I026458 as one parent share the identical feature of having the genetic complement of I026458 (Appeal Brief, paragraph bridging

pages 10-11). However, the function of the product claimed in *Eli Lilly* was known. In the instant application, the specification does not describe the function of the claimed hybrids, and does not correlate the function of the hybrids with the structure of the I026458 genome. Furthermore, the genetic complement of the other unknown parent has not been described, and hence Applicant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred I026458 with any and all other inbred or hybrid corn plants.

Applicant argues that the claimed F1 hybrid plants having I026458 as one parent will share the same genetic complement from I026458 and is readily identifiable by the genetic marker analysis in Tables 6 and 8. Applicant argues that hybrid corn plant 7041221 has the SSR genetic marker profile of I026458 and includes the genetic markers from the second parent plant, and that this will be true for any other hybrid plant having I026458 as one parent, save for “an occasional difference at a locus due to spontaneous genetic rearrangements” (Appeal Brief, page 11, 1st full paragraph and page 14, 1st full paragraph). However, while all of the claimed hybrids will inherit the SSR marker profile of I026458, they will not inherit the same genetic markers from the other parent, as did hybrid 7041221, because they will have different parents. The SSR marker profile of the other parents are not described. Further, the description of corn plant 7041221 does not describe the morphological and physiological traits of all other corn plants that can be produced by crossing I026458 to any other corn plant. One skilled in the art cannot identify all of the morphological and physiological characteristics of corn plant 7041221 that also definitely will be expressed by all other members of the genus, nor can one identify the characteristics that will be different. Further, while hybrid 7041221 has inherited the SSR

marker profile of I026458, the specification does not describe the traits that are correlated with these markers. The traits expressed by 7041221 are not solely due to the presence of the alleles associated with the SSR markers, or the genetic contribution of I026458.

Applicant continues, arguing that the second plant that is used to make the hybrid is irrelevant. Because any second plant capable of reproduction may be used to make the hybrid, Applicant argues that the claimed hybrids cannot be said to lack written description for the second genetic complement (Appeal Brief, paragraph bridging pages 11-12 and page 12, 1st full paragraph). However, the genes that the hybrids inherit from I026458 will not solely determine the traits that are expressed. The traits, and therefore the functions of the hybrids, are determined by the interaction of the products of the genes inherited from I026458 with the products of the genes inherited from the other parent. The contributions of the other parent cannot simply be disregarded.

Regarding the issue that information regarding the morphological and physiological traits of the hybrid plants has not been provided, Applicant argues that he has gone beyond the morphological and physiological traits by describing the claimed hybrid plants at the genetic level, and that a better description could not be made than at the genetic level, and that the entire genetic complement of parent plant I026458 is described by way of a seed deposit (Appeal Brief, page 13, 1st full paragraph and the paragraph bridging pages 13-14). However, as discussed above, the specification does not correlate any function of the claimed hybrids with this genetic information. The specification does not correlate any traits with any genes or molecular markers of I026458. Further, while I026458 seed has been deposited, none of the hybrid seeds, which produce plants having traits and functions that are different from I026458, have been deposited.

In response to the issue raised in the previous Office action, that other plants may share genetic marker data and that primer sequences are not described, Applicant argues that no effort was made to show that any substantial number of marker loci actually are shared by other plants (Appeal Brief, paragraph bridging pages 12-13). However, the specification shows that at least two other inbred corn plants share many of the same loci (see Table 6). Further, the specification does not explain why the SSR data of inbreds 85DG1 and 84BRQ4 were chosen for comparison with that of I026458 in Table 6, how related these inbreds are to I026458, and hence how useful the SSR markers are for distinguishing maize lines. Also, the specification does not mention anything concerning the traits expressed by the 85DG1 and 84BRQ4 plants, and how similar those traits are to the combination of traits expressed by I026458.

Regarding claims drawn towards corn plant I026458 containing single locus conversions: Applicant appears to be arguing that the specification describes such plants, simply because the definition of “single locus converted plants” provided in the specification indicates that such plants possess essentially all of the desired morphological and physiological characteristics of plant I026458 in addition to the characteristics conferred by the single locus transferred (Appeal Brief, page 15, 1st full paragraph). However, the specification does not describe the characteristics expressed by the claimed plants. The specification does not describe any and all single locus conversion traits, nor the source of said traits. The traits conferred by the single locus may change one or more of the traits expressed by I026458. Further, the descriptions of plants that express “essentially” all of the “desired” characteristics of I026458 are not described. Further, the term “essentially” in the definition for “single locus converted plant” indicates that, in addition to the trait conferred by the single transferred locus, the plant does not have to

express every one of the traits that the specification provides in its description of I026458. The definition also indicates that the plants only have to possess the “desired” characteristics of I026458, not all of them. The “desired,” as opposed to the “undesired,” traits are unknown. Backcross converted plants that do not have all of the morphological and physiological traits of I026458 are not described by the specification, or the deposit of I026458 seed.

Applicant cites *In re Gosteli* for indicating that the written description requirement does not require an applicant to describe exactly the subject matter claimed, but that the description must clearly allow persons of ordinary skill in the art to recognize what is claimed (Appeal Brief, page 15, 1st full paragraph). However, the specification does not describe the traits expressed by all of the claimed plants, nor what set of traits are present in all of the claimed plants to allow persons of ordinary skill in the art to recognize the claimed plants. As discussed, the specification does not describe plants that express only some or “desired” traits that are expressed by I026458, or how to distinguish such plants from I026458. Further, single loci, for example those encoding a transcription factor, may affect one or more traits expressed by I026458. The claimed plant then would not express all of the traits of I026458. Such plants are not described by the specification.

Applicant continues, arguing that undiscovered genes are not claimed, and that the fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant, because it is the single locus conversion of corn plant I026458 that is claimed (Appeal Brief, paragraph bridging pages 15-16). However, if a gene has not been discovered or isolated at the time the instant application was filed, Applicant cannot be in possession of a corn plant into which this gene was deliberately introduced.

Applicant argues that the Examiner supposedly ignored evidence submitted in the prior response that the specification recites numerous single locus traits with a publication reference or patent number. Applicant goes on to provide several examples (Appeal Brief, page 16, 1st full paragraph to page 18, 1st full paragraph). However, this argument was addressed on pages 7 and 8 of the Office action mailed 23 January 2003. While the specification does cite references that describe numerous isolated genes, not all of the cited references actually teach that certain genes have been discovered or isolated. For example, the references cited in the specification do describe isolated single genes or loci that confer yield enhancement or yield stability. If such single loci have not been discovered or isolated, Applicant cannot be in possession of I026458 plants comprising this single locus conversion. The claims broadly encompass plant I026458 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a trait. Applicant cannot be in possession of plants further comprising single locus conversions that have yet to be identified.

Applicant argues that, under the Examiner's reasoning, any claim could be read to encompass subject matter yet to be invented and therefore not described. For example, a corn plant transformed with a *Bacillus thuringiensis* gene (presumably encoding the insecticidal endotoxin) would be invalid because it would encompass corn varieties yet to be discovered (Appeal Brief, paragraph bridging pages 15-16). In this example, however, there is only one genetic structure that is relevant, that of the *B. thuringiensis* gene, and only one function, that of the insecticidal properties conferred by the product of the gene. A claim drawn towards a corn plant containing the gene is described, because the structure and function of the gene is described. The corn plant comprising that gene has increased resistance against insects. In the

instant application, the invention encompasses corn seed I026458 and the plant produced by it. The deposit of the seed satisfies the written description requirement, and the functions of the plant are described in Tables 1-3. Another locus that is introduced into I026458 would change the traits, and therefore the functions, of I026458.

Applicant argues that techniques for the introduction of single locus traits by genetic transformation were well known (Appeal Brief, page 19, 1st full paragraph). That methods to produce genetically transformed corn plants existed at the time of the invention is, of course, not disputed. However, methods for producing a product do not describe the product itself.

Regarding claim 31: Applicant disagrees with the legal contention that products made in intermediate steps of method claims must be described, and argue that this is a misstatement of the law (Appeal Brief, paragraph bridging pages 19-20 and page 20, 1st full paragraph). Applicant continues, arguing that a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products, and that the starting materials must be provided, otherwise the process could not be completed (Appeal Brief, page 22, 1st full paragraph to page 23, 1st full paragraph). Applicants are directed to 64 Fed. Reg. 71427, 71428 (1999), comment No. 4, wherein application of the written description guidelines to methods have been adapted. The claimed methods require that further steps be conducted with the intermediate products. These products are not described, for the reasons discussed above. The process cannot be completed in the absence of the intermediate products. Hence, because the intermediate products are not described, the complete method necessarily is not described.

7. Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards inbred corn plant I026458 further defined as having a genome comprising any single locus conversion; or wherein the single locus was stably inserted into a corn genome by transformation.

The specification teaches that single locus conversions of the disclosed corn plant refers to plants that are developed through backcrosses wherein essentially all of the desired morphological and physiological characteristics of the inbred are recovered in addition to a single locus transferred by the backcrossing technique (paragraph bridging pages 29-30). However, the specification does not teach any I026458 plants comprising single locus conversions produced by crossing. The specification at pages 35-36 provides a summary of the crosses performed to introduce a locus into a DEKALB proprietary inbred corn plant. However, there is no indication that all of the morphological and physiological traits of the DEKALB proprietary inbred corn plant were recovered, and that only one single locus was transferred from the donor parent.

It is not clear that single loci may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (*Theor. Appl. Genet.*, 2000, Vol. 101, pages 323-326), and Eshed et al. (*Genetics*, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic

background of a different plant, to confer a desired phenotype in said different plant.

Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

The specification also teaches that single loci may be introduced by transformation (page 33, line 1-10). Claim 28 recites the recitation, “wherein the single locus was stably inserted into a corn genome by transformation” (emphasis added). This recitation does not clearly indicate that it was plant I501150 that was transformed. The claim encompasses the embodiment that another corn plant was transformed, and that the single locus was introduced into I501150 by backcrossing.

If claim 28 is directed to I026458 plants into which a single locus was directly introduced by transformation, the specification does not enable transforming I501150 cells with all types of transgenes. As broadly interpreted, the claimed plants and method encompass introducing any type of transgene into I026458, including those that have not been isolated at the time the application was filed. Claims 27-29 also encompass loci whose functions are unknown. One skilled in the art would not know how to use plants containing such loci. Single loci have also not been identified in the art for all of the traits listed in claim 30, as discussed above. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by “its physical or chemical properties” (e.g. a DNA sequence). Further, if the effect of transgene expression in I026458 were unknown, one skilled in the art would not know how to use the transformed plant. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Furtherstill, the effects of transgene expression on the traits expressed by untransformed I026458 are unknown. The specification does not teach one how to use a transformed I026458 plant if all of the morphological and physiological traits of I026458 are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

8. Claims 1, 5, 7-10, 12, 13, and 21 are allowed. Claims 2-4, 6, 11, 14-20, and 22-31 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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